

8155-5

9-26-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Canberra Corporation
3610 Holland-Sylvania Rd.
Toledo, OH 43615

SEP 28 2000

Subject: General Purpose/Non-Acid G/P Disinfectant Cleaner
EPA Registration No. 8155-5
Letter Dated March 28, 2000

Attn: John Wiegand
Director of Research

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided you delete the organism "Streptococcus faecalis-Vancomycin Resistant (VRE) " from the label. It was not on the Agency's last accepted stamp label and may not be added without the submission and acceptance of specific efficacy data by the Agency. The findings are follows:

1. There was no substantiating data in the aforementioned Stepan file to support the antibiotic resistant claim requested by you.
2. The agency contacted the CDC directly to obtain antibiotic resistance testing records on the organism Staphylococcus aureus, HIP-5836. Documentation supplied confirms that the organism shows an intermediate level of resistance to the antibiotic vancomycin and teicoplanin, both of which are glycopeptides, when both dilution methods are used for determination of resistance.
3. Previously, CDC changed the designation of Vancomycin-Resistant Staphylococcus aureus (VRSA) to Vancomycin Intermediate Staphylococcus aureus (VISA). Recently, that designation has been changed to Glycopeptide-Resistant Staphylococcus aureus (GRSA).
4. Your request to add Glycopeptide-Resistant Staphylococcus aureus (GRSA) to the label claims is approved.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label before this product is released for shipment.

CONCURRENCES

SYMBOL	7510W						
SURNAME	John Wiegand						
DATE	9-15-00						

If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)

Amended Label\Sep. 21, 1999\EPA Reg. No. 8155-5

RESPONSE TO AGENCY LETTER DATED MAR. 6, 2000

***GENERAL PURPOSE/NON-ACID**

HUSKY *G/P DISINFECTANT CLEANER

**BACTERICIDAL TUBERCULOCIDAL *VIRUCIDAL
CLEANS DISINFECTS DEODORIZES
ANTIBACTERIAL ANTI-MICROBIAL
NON-ACID DISINFECTANT BOWL & BATHROOM CLEANER**

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

SEP 26 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 8155-5

Kills Herpes Simplex Type 2*

Kills HIV-1(AIDS VIRUS) on precleaned environmental surfaces*

Kills Methicillin Resistant Staphylococcus aureus (MRSA)

Kills Vancomycin Resistant Staphylococcus aureus(VRSA)

Kills Escherichia coli (O157:H7)

Kills Streptococcus faecalis-Vancomycin Resistant (VRE)

Cuts Through Dirt and Grease Cleans Soap Scum and Hard Water Films

**GERMICIDAL/MILDEWSTAT(ON HARD INANIMATE SURFACES)/
FUNGICIDAL/THICK FOAMING FORMULA**

ACTIVE INGREDIENTS

n-Alkyl(60% C14, 30%C16, 5%C12, 5%C18)

dimethyl benzyl ammonium chlorides.....0.105%

n-Alkyl(68%C12, 32%C14) dimethyl ethylbenzyl ammonium chlorides.....0.105%

INERT INGREDIENTS99.790%

TOTAL.....100.000%

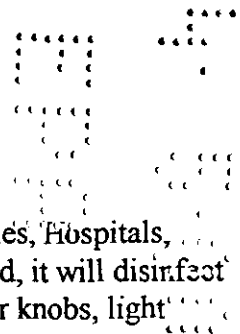
KEEP OUT OF REACH OF CHILDREN

CAUTION

See reverse side for Statement of Practical Treatment and additional precautionary statements.

Net Contents: One Quart (32 Fl. Oz.) 946 ml

Manufactured by: Canberra Corporation
Toledo, Ohio 43615



Designed specifically for institutional cleaning and disinfection in Nursing Homes, Hospitals, Institutions, Offices, Homes, Schools, Hotels and Motels. When used as directed, it will disinfect inanimate hard surfaces (such as walls, sink tops, tables, chairs, telephones, door knobs, light switches, shower stalls, hampers and cabinets).

With all the news about germs and bacteria, just looking clean isn't good enough. This product does it all – cleans, disinfects and deodorizes your bathroom and toilet bowl, even under the rim. Antibacterial formula kills common household germs such as Staphylococcus aureus(Staph), Streptococcus faecalis(Strep), Escherichia coli(E. coli) and Salmonella choleraesuis(Salmonella) and quickly eliminates annoying odors, leaves a light fresh scent. Will not harm plumbing or septic tanks. This product is a combination of effective cleaners, plus antibacterial disinfectants, so you can be sure your bowl is completely clean.

Bactericidal Activity - When used as directed this product exhibits effective disinfectant activity against the organisms: Mycobacterium tuberculosis (BCG) at 20° C, Staphylococcus aureus, Staphylococcus aureus-Methicillin Resistant(MRSA), Salmonella choleraesuis, Pseudomonas aeruginosa, Streptococcus faecalis-Vancomycin Resistant(VRE), Staphylococcus aureus-Vancomycin Resistant(VRSA), and Escherichia coli(O157:H7)

Efficacy tests have demonstrated it to be an effective one-step cleaner-disinfectant in the presence of organic soil(5% blood serum).

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FOR CLEANING AND DEODORIZATION: To clean light soil from hard surfaces, dilute one part product with seven parts water. Spray and wipe clean.

DISINFECTION AND CLEANING: To disinfect, clean and deodorize hard non-porous surfaces such as toilet seats, bathroom tiles, fixtures, shower stalls, tables hand rails, walls and sinks, proceed as indicated below: Spray area until it is covered with solution. Allow the product to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop or sponge. The product will not leave grit or soap scum. For disinfection, remove heavy soil before treatment. One step cleaning and disinfection of toilet bowls and urinals: Remove water from bowl or urinal. Apply one to two ounces of this product evenly, allowing sufficient time for product to cover entire surface of bowl for best cleaning results. Swab bowl completely using brush or bowl mop, making sure to get under the rim. Let stand for 10 minutes and flush.

MOLD AND MILDEWSTAT - Prevents and controls mold and mildew on hard non-porous inanimate surfaces. **MILDEWSTAT** - To control mold and mildew on hard non-porous surfaces (such as floors, walls, table tops), spray the surfaces to be treated, making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

This product is fungicidal against pathogenic fungi (T. mentagrophytes) when used as directed on hard surfaces found in the restroom, shower stall and locker room or other clean hard non-porous surfaces commonly contacted by bare feet.

EFFECTIVE AGAINST HERPES SIMPLEX TYPE 2 (on hard inanimate surfaces).

EFFECTIVE AGAINST HIV-1 (AIDS VIRUS): Product was evaluated and found to be an effective virucide in the presence of 5% serum against the virus HIV-1(Human Immunodeficiency Virus 1, commonly referred to as "AIDS VIRUS" on inanimate surfaces.

KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces or objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1(HIV-1)(associated with AIDS).

ACCEPTED
with COMMENTS
in EPA Letter Dated

SEP 26 1990

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 8155-5

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES/OBJECTS SOILED WITH BLOOD /BODY FLUIDS:

Personal Protection: Disposable latex gloves, gowns, masks and splash resistant goggles must be worn when handling items soiled with blood or body fluids. **Cleaning Procedures:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Leave surface wet for 10 minutes. **Disposal of Infectious Material:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Avoid breathing spray mist. Avoid contact with skin, eyes or clothing.

Statement of Practical Treatment: In case of eye contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Get medical attention if irritation persists. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink large quantities of water. Call a physician.

STORAGE AND DISPOSAL

PROHIBITIONS: DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL. OPEN DUMPING IS PROHIBITED. **Pesticide Disposal** - Pesticide spray mixture or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Sub-Title C of the Resource Conservation and Recovery Act. **Container Disposal** - Do not reuse empty container. Rinse thoroughly with water before discarding in trash.

EPA REG. NO. 8155-5 EPA EST. NO. 8155-OH-1
U.S. PATENT NO. 5,444,094

Keep From Freezing

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in EPA Letter Dated:

SEP 26 2000

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